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**MENTOR H/S, INC. (now known as Mentor Texas Inc.), and SONIQUE SURGICAL
SYSTEMS, INC., Plaintiffs-Appellants, v. MEDICAL DEVICE ALLIANCE, INC.,
LYSONIX, INC., and MISONIX, INC., Defendants-Cross Appellants.**

99-1532, 00-1165

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

244 F.3d 1365; 2001 U.S. App. LEXIS 6033; 58 U.S.P.Q.2D (BNA) 1321

April 9, 2001, Decided

PRIOR HISTORY: [**1] Appealed from: United States District Court for the Central District of California. Judge William D. Keller. *Mentor H/S, Inc. v. Medical-Device Alliance, Inc.*, 1999 U.S. Dist. LEXIS 23400 (C.D. Cal., June 10, 1999)

DISPOSITION: AFFIRMED-IN-PART and REVERSED-IN-PART.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff corporation appealed from the judgment of the United States District Court for the Central District of California, granting judgment as a matter of law, but denying a new trial to defendant corporations, in plaintiff's action alleging patent infringement.

OVERVIEW: Plaintiff corporation brought a patent infringement action against defendant corporations regarding a method for ultrasonic assisted liposuction. The jury rendered a verdict for plaintiff of direct, contributory, and inducement of infringement. The trial court granted defendant corporations' motion for judgment as a matter of law, but denied their motion for a new trial. The trial court denied plaintiff's motion for enhanced damages and attorney fees. On appeal, the court reversed, holding that substantial evidence supported the jury's verdict that plaintiff did not violate the best mode requirement of 35 U.S.C.S. § 112, and that the jury's verdicts on anticipation, obviousness, and inequitable conduct were not against the great weight of the evidence. The court further held that substantial evidence supported the jury's verdict that defendant induced infringement of and contributorily infringed plaintiff's patent. The court affirmed the denial of plaintiff's motion for enhanced damages and attorney fees.

OUTCOME: Judgment was reversed in part because sub-

stantial evidence supported the jury's verdict for plaintiff corporation of direct, contributory, and inducement of infringement by defendant corporations. Judgment was affirmed in part because the denial of plaintiff's motion for enhanced damages and attorney fees was proper.

LexisNexis(R) Headnotes

Civil Procedure > Parties > Joinder > Permissive Joinder [HN1] The use of appellate joinder under *Fed. R. Civ. P. 21* is allowed when a change in the parties will not affect the litigation or embarrass the defendant.

Civil Procedure > Trials > Judgment as Matter of Law > General Overview

Civil Procedure > Appeals > Standards of Review > De Novo Review

Civil Procedure > Appeals > Standards of Review > Substantial Evidence > Sufficiency of Evidence

[HN2] The district court may grant a judgment as a matter of law (JMOL) when a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue. *Fed. R. Civ. P. 50(a)(1)*. The appellate court reviews a district court's decision granting a motion for JMOL de novo, reapplying the JMOL standard. On appeal, the appellate court must consider the record evidence in the light most favorable to the non-movant and draw all reasonable inferences in its favor without disturbing the jury's credibility determinations or substituting our resolutions of conflicting evidence for those of the jury. The appellate court will affirm the grant of JMOL if substantial evidence does not support the jury's factual findings or if those factual findings do not support the jury's legal conclusions.

Civil Procedure > Judgments > Relief From Judgment > Motions for New Trials

Civil Procedure > Appeals > Standards of Review >

Abuse of Discretion

[HN3] Whether a new trial was properly granted is a procedural issue not unique to patent law; the appellate court therefore reviews the trial court's grant of a new trial under the law of the regional circuit. In the Ninth Circuit, a grant of a new trial is reviewed for an abuse of discretion.

Civil Procedure > Judgments > Relief From Judgment > Motions for New Trials***Civil Procedure > Appeals > Standards of Review > Abuse of Discretion******Evidence > Procedural Considerations > Weight & Sufficiency***

[HN4] The trial court may grant a new trial, even though the verdict is supported by substantial evidence, if the verdict is contrary to the clear weight of the evidence, or is based upon evidence which is false, or to prevent, in the sound discretion of the trial court, a miscarriage of justice. The appellate court must uphold the district court if any of its grounds for granting a new trial are reasonable. The corollary, of course, is that a district court may not grant or deny a new trial merely because it would have arrived at a different verdict. Thus, the appellate court may find that a district court abused its discretion in ordering a new trial if the jury's verdict is not against the clear weight of the evidence.

Civil Procedure > Judgments > Relief From Judgment > Motions for New Trials***Evidence > Procedural Considerations > Weight & Sufficiency***

[HN5] When a motion for a new trial is based on insufficiency of the evidence, the court should grant the motion only if the verdict is against the great weight of the evidence, or it is quite clear that the jury has reached a seriously erroneous result. When granting a new trial, a trial court may weigh the evidence and credibility of the witnesses, but it may not grant a new trial merely because it might have come to a different result from that reached by the jury.

Patent Law > Claims & Specifications > Best Mode > Fact & Law Issues***Patent Law > Date of Invention & Priority > General Overview******Patent Law > Infringement Actions > Defenses > Patent Invalidity > Fact & Law Issues***

[HN6] A patent specification must set forth the best mode contemplated by the inventor of carrying out his invention. 35 U.S.C.S. § 112, P 1. Determining whether a patent fails to comply with the best mode requirement and is thus invalid involves two factual inquiries. First, the fact-finder must determine whether at the time an applicant filed an application for patent, he or she had a best

mode of practicing the invention, which is a subjective determination. Second, if the inventor had a best mode of practicing the invention, the fact-finder must determine whether the best mode was disclosed in sufficient detail to allow a skilled artisan to practice it without undue experimentation, which is an objective determination.

Evidence > Procedural Considerations > Burdens of Proof > General Overview***Patent Law > Inequitable Conduct > General Overview******Patent Law > Infringement Actions > Defenses > Patent Invalidity > Fact & Law Issues***

[HN7] Defendants bear the burden of showing facts supported by clear and convincing evidence to prove a patent invalid. Courts grant judgment as a matter of law for the party bearing the burden of proof only in extreme cases, when the party bearing the burden of proof has established its case by evidence that the jury would not be at liberty to disbelieve and the only reasonable conclusion is in its favor.

Patent Law > Claims & Specifications > Best Mode > General Overview

[HN8] The best mode requirement does not mandate the disclosure of each detail of prototypes made prior to filing for a patent.

Patent Law > Claims & Specifications > Best Mode > General Overview

[HN9] An applicant is only obliged to disclose unclaimed elements when they are necessary to the operation of the invention.

Patent Law > Anticipation & Novelty > Accidental Anticipation & Inherency

[HN10] The threshold for showing inherent anticipation may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

Patent Law > Inequitable Conduct > Burdens of Proof***Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > Elements***

[HN11] A defendant asserting an inequitable conduct defense must demonstrate by clear and convincing evidence that the applicant or his attorney failed to disclose material information to the United States Patent and Trademark Office (PTO), and that the applicant or his attorney did so with intent to deceive the PTO. Inequitable conduct is an equitable issue committed to the discretion of the district court.

Criminal Law & Procedure > Trials > Judicial Discretion

***Criminal Law & Procedure > Scienter > Willfulness
Criminal Law & Procedure > Appeals > Standards of
Review > Abuse of Discretion > General Overview***

[HN12] Assessing increased damages is a two-step process. First, the fact-finder must determine if an accused infringer is guilty of conduct, such as willfulness, upon which increased damages may be based. If so, the court then exercises its discretion to determine if the damages should be increased given the totality of the circumstances.

COUNSEL: Frank E. Scherkenbach, Fish & Richardson, P.C., of Menlo Park, California, argued for plaintiffs-appellants. With him on the brief were Robert E. Hillman, Fish & Richardson, of Boston, Massachusetts; and Richard J. Anderson and John A. Dragseth, Fish & Richardson, of Minneapolis, Minnesota.

Matthew D. Powers, Weil, Gotshal & Manges LLP, of Menlo Park, California, argued for defendants-cross appellants. With him on the brief were Steven S. Cherensky, Christopher J. Cox, and Nancy K. Raber.

JUDGES: Before MAYER, Chief Judge, LOURIE and SCHALL, Circuit Judges.

OPINIONBY: LOURIE

OPINION: [*1369]

LOURIE, Circuit Judge.

Mentor H/S, Inc. appeals from the decision of the United States District Court for the Central District of California, following a jury verdict of direct, contributory, and inducement of infringement of Mentor's U.S. Patent 4,886,491 by Medical Device Alliance, Inc. ("MDA"), Lysonix, Inc., and Misonix, Inc. (collectively, "the defendants"). The court (1) granted the defendants' motion for judgment as a matter of law ("JMOL") [**2] that a best mode violation occurred; (2) granted Misonix's motion for JMOL that it did not infringe Mentor's patent; (3) granted a conditional new trial (in the event that this court reverses its JMOL on the best mode issue) for anticipation, obviousness, inequitable conduct, [*1370] and contributory infringement by all defendants; and (4) denied Mentor's motion for enhanced damages and attorney fees. *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, No. CV 97-2431-WDK (C.D. Cal. June 10, 1999) (granting JMOL on the best mode ground and non-infringement by Misonix, and denying motion for damages and fees) ("Mentor I"); *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, No. CV 97-2431-WDK (C.D. Cal. Nov. 19, 1999) (granting new trial motions) ("Mentor II"). Mentor chal-

lenges each of these rulings on appeal. The defendants cross-appeal the district court's denial of their motion for a new trial on claim construction and request a judgment of non-infringement based on their proposed claim construction.

Because substantial evidence supports the jury's verdict that the inventors did not violate the best mode requirement of 35 U.S.C. § 112 (1994), first paragraph, [**3] we reverse the district court's grant of JMOL on that issue. We also reverse the court's grant of a new trial on anticipation, obviousness, and inequitable conduct because the jury's verdicts on those issues were not against the great weight of the evidence. We further conclude that substantial evidence supports the jury's verdict that Misonix induced infringement of and contributorily infringed Mentor's patent and accordingly reverse the court's JMOL of non-infringement with respect to Misonix. We also reverse the district court's grant of a new trial on contributory infringement by all defendants. However, we affirm the court's denial of Mentor's motion for enhanced damages and attorney fees.

Finally, we reject the defendants' cross-appeal from the court's denial of their motion for a new trial on claim construction and dismiss their remaining arguments for, inter alia, JMOL on additional best mode issues and a new trial on inducement of infringement by Lysonix and MDA. Accordingly, we affirm-in-part and reverse-in-part.

BACKGROUND

A. The Patent

Mentor is the exclusive licensee of the '491 patent, which relates to a method for ultrasonic assisted liposuction. In the claimed [**4] method, fatty tissue is melted by heat produced from ultrasonic vibrations and then removed by suction. Misonix manufactures the ultrasonic device, "Lysonix 2000," that is used in the accused method. MDA and its subsidiary, Lysonix, buy the devices from Misonix and sell them to doctors who perform the allegedly infringing method. Claim 1, the only claim at issue, reads as follows:

1. A method of removing animal fatty tissue from a patient in vivo comprising the steps of:

inserting an aspirating probe into the body in an area between the flesh and the muscle in the area of the fatty tissue;

ultrasonically vibrating said probe at substantially high frequencies and low amplitudes, creating localized tissue separation

and frictional heat;

melting at least some of said fatty tissue by said localized heat, so as to provide more efficient removal of said fatty tissue;

irrigating the area surrounding the probe;

emulsifying said fatty tissue; and

aspirating the emulsified fatty tissue by applying suction, whereby a slimmer profile is provided.

'491 patent, col. 6, ll. 35-49.

B. District Court Litigation

Mentor sued each defendant for direct, contributory, and inducement [*5] of infringement, asserting that such infringement was willful. The jury returned a verdict that each of the defendants had willfully engaged in all three kinds of infringement. The jury also found by special verdict that the defendants did not prove by clear and convincing evidence that the patent was invalid for anticipation or obviousness, or [*1371] that the patent was unenforceable due to the inventors' failure to disclose material information during prosecution. The defendants challenged the jury's verdict in a series of post-trial motions asserting patent invalidity, unenforceability, and non-infringement.

The court granted defendants' motion for JMOL on the best mode ground for failure to disclose a preferred frequency stabilizing circuit. Mentor I at 2-4. During cross examination, one of the inventors, Tulio Parisi, testified as follows:

Q. So you agree it was important to have that circuitry that locked the frequency? You are not changing your deposition testimony then?

1. I'm saying that when we applied the probe to a different level of adipose tissue, or fat tissue, fatty tissue, at times if we didn't have the amplitude or the power level set, we would not get [*6] the type of frictional heat that we desired.

2. My question, Mr. Parisi, is that you thought that circuit which stabilized the frequency was important to make your ultrasonic liposuction device function the way you wanted it to; isn't that true?

3. At the time, yes.

Id. at 2-3. The district court found, based solely on that brief testimony, that the defendants had shown by clear and convincing evidence that Parisi did not adequately disclose in the patent the frequency stabilization circuit and hence that he violated the best mode requirement. Id. at 4.

The district court also granted the defendants' post-trial motions for a conditional new trial on anticipation and obviousness, stating that the jury's verdict on validity was against the great weight of the evidence. Mentor II at 3. Specifically, the district court found that U.S. Patent 3,589,363 teaches every limitation claimed in the '491 patent in its step-by-step description of a device used to remove unwanted soft tissue. Id. The '363 patent relates to a phacoemulsifier device especially suitable for cataract removal. '363 patent, col. 1, ll. 42-44. At trial, the defendants asserted that the [*7] '363 patent inherently teaches that unwanted tissue such as fat is melted because heat is expelled by electrical-to-mechanical energy conversion in the device's hand piece. Mentor contested this inherent anticipation argument by presenting testimony from Dr. Langer that the device in the '363 patent generated less heat than that produced in the claimed method. The defendants sought to rebut this testimony on cross examination as follows:

1. And you believe it's probably about the same amount of heat, but you haven't tested it; right?

2. Right. Wait a second. I didn't say it was probably the same amount of heat.

3. That's what I heard, Dr. Langer.

4. That's not what I said.

1. And if it's the same amount of heat, then it would melt at least some of said fatty tissue, because that's what Parisi teaches, right?

2. Yes.

3. And you have no reason to believe in the context of the Banko/Kelman '363 patent that it's any less heat than what Parisi generates, do you?

4. Yes, I do.

5. And what's that basis?

6. Well, the Parisi system is a much larger, more powerful system, larger probe.

7. And does the Banko/Kelman patent teach [**8] that the probe has to be any particular size?

8. I believe at that time, the probe sizes were generally much smaller.

9. Does the Banko/Kelman patent teach that the probe needs to be any particular size?

10. I don't recall that it does. On the other hand, if you use some of the [**1372] criteria that you have been using, maybe it does.

The jury nonetheless found the patent not invalid.

The court also found that the Cavitron 1978 and 1980 510(k) FDA applications identified each element necessary for finding anticipation, including the use of the devices for liposuction. Mentor II at 3. The FDA applications described the use of the Cavitron USA devices to fragment brain tumor tissue and suggested other possible applications for those devices, one of which was subcutaneous lipectomy, or liposuction.

The defendants also asserted in their post-trial motions that the '491 patent is unenforceable for inequitable conduct on the ground that the applicants failed to disclose material prior art to the United States Patent and Trademark Office ("PTO") during prosecution with intent to deceive. The jury determined that the applicants did not fail to disclose material information [**9] to the PTO, and thus did not reach the question of intent to deceive. The district court concluded that the '363 patent was material and that the jury's verdict was against the great weight of the evidence because Parisi copied some language from this patent, almost word for word, into his invention disclosure statement, but then failed to disclose the '363 patent to the PTO. Mentor II at 4. The district court also concluded that the jury's verdict was against the great weight of the evidence because Parisi asserted in his 510(k) application to the FDA that his prototype was similar in design to the Cavitron device, but then failed to disclose his opinion regarding the similarity of the products to the PTO during prosecution of the '491 patent. Id.

Although the jury found that all three defendants infringed directly, contributorily, and by inducement, the district court granted Misonix, the manufacturer of the

device used in the accused method, a JMOL of non-infringement. The court held that (1) there had been no showing that Misonix had sufficiently performed the patented method to support a finding of direct infringement; (2) with regard to contributory infringement, no [**10] reasonable juror could conclude that Lysonix 2000 was especially adapted for infringing the '491 patent, because it was suitable for a wide range of surgical applications, not just liposuction; and (3) with regard to inducement of infringement, Mentor only offered evidence indicating that Misonix knew that its products would be used for liposuction, but not that they would necessarily be used in the patented method. Mentor I at 4-5.

The defendants also moved for a new trial on contributory infringement and inducement of infringement. The court granted a new trial on contributory infringement because, in its view, the "defendants presented extensive testimony indicating their products were suitable for a wide range of surgical applications," and thus were not especially adapted for use in the infringing method. Mentor II at 2. The court denied the defendants' motion for a new trial on inducement of infringement, stating that substantial evidence indicated that MDA and Lysonix knew that their actions would induce actual infringement. Id. The court indicated, however, that it granted a new trial to Misonix in light of its earlier grant of a JMOL for Misonix on this issue. [**11]

The district court also denied Mentor's motion for enhanced damages under 35 U.S.C. § 284 (1994), which provides that "the court may increase the damages up to three times the amount found or assessed." Mentor I at 7. Although the jury found that the defendants willfully infringed the patent, the court declined to assess enhanced damages because it determined that the question of willfulness was close, based on the evidence. Id. The court also declined to award attorney fees to Mentor as the prevailing party under 35 U.S.C. § 285 (1994). Id.

Finally, the district court denied the defendants' motion for a new trial on claim construction, stating that the defendants [**1373] only repeated arguments previously raised and rejected. Mentor II at 2-3.

DISCUSSION

A. Standing

Although neither party raised the issue, either at the district court level or on appeal, we have questioned whether Mentor, as exclusive licensee, possessed sufficient rights under its license to sue without joining Sonique, its licensor. We invited and received briefs on the issue. We then decided in *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 240 F.3d 1016, 57 U.S.P.Q.2D

(BNA) 1819 (Fed. Cir. 2001), [**12] that Mentor did not have sufficient rights under its exclusive license to sue in its own name without joining the patentee, Sonique Surgical Systems, Inc., and we invited and subsequently entertained Mentor's motion to join Sonique as a party pursuant to Fed. R. Civ. P. 21. Mentor argued that we should join Sonique because its joinder would not prejudice the defendants. The defendants argued that this case does not present the kind of rare circumstances that may justify appellate joinder, citing *Prima-Tek II v. A-Roo Co.*, 222 F.3d 1372, 1377, 55 U.S.P.Q.2D (BNA) 1742, 1749 (Fed. Cir. 2000). The defendants also argued that they would be prejudiced because they could have sought discovery from Sonique regarding a reasonable royalty for both Sonique and Mentor had Sonique been joined earlier.

We have now issued an order granting Mentor's motion to join Sonique because such joinder would not prejudice the defendants. *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 2001 U.S. App. LEXIS 9282, Nos. 99-1532, 00-1165 (Fed. Cir. Mar. 20, 2001) (order). Appellate joinder under Fed. R. Civ. P. 21 is sanctioned by both the Supreme Court and the Ninth Circuit, which is the source of the procedural law that governs [**13] this non-patent issue, *Southwest Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280, 1290, 56 U.S.P.Q.2D (BNA) 1161, 1168 (Fed. Cir. 2000). See *Newman-Green, Inc. v. Alfonzo-Larrain*, 490 U.S. 826, 837, 104 L. Ed. 2d 893, 109 S. Ct. 2218 (1989) (approving [HN1] the use of Rule 21 by appellate courts when a change in the parties will not affect the litigation or embarrass the defendant); *Cal. Credit Union League v. City of Anaheim*, 190 F.3d 997, 998 (9th Cir. 1999) (allowing the appellate joinder of a plaintiff to retroactively cure a jurisdictional defect).

We permitted joinder of Sonique because we are not persuaded by defendants' arguments that we should dismiss this case for lack of jurisdiction, as we did in *Prima-Tek*. In *Prima-Tek*, we decided that joinder would have prejudiced A-Roo because it was unable to conduct discovery on the non-joined party. *Id.* Here, the defendants did conduct discovery on Sonique's principals, Parisi and Massengill. Although the defendants did not depose Parisi and Massengill regarding Sonique's claim for damages, we are not persuaded that any evidence about such a claim would have altered the reasonable royalty [**14] selected by the jury. Sonique's only "claim" for damages is measured by Mentor's claim for damages. Sonique's only sales were to Mentor. See Exclusive Evaluation and Distribution Agreement of April 19, 1994 at § 4.1.1; Addendum to Exclusive Distribution Agreement at D. Mentor is entitled to receive all infringement damages on the basis of the license agreement, and Sonique's remedy for any damages it has suffered are provided for un-

der the agreement as well. See Exclusive Evaluation and Distribution Agreement of April 19, 1994 at § 5.4.2 (b). Sonique has no further damages.

Moreover, unlike in *Prima-Tek*, where A-Roo challenged standing at trial, *Prima-Tek*, 222 F.3d at 1381, 55 U.S.P.Q.2D (BNA) at 1749, no party here raised the issue of standing in this case, even on appeal. We addressed this question only to satisfy our own jurisdictional obligation. In sum, we have ordered the joinder of Sonique because such joinder cures a technical jurisdictional defect and will not prejudice the defendants. Having satisfied ourselves that jurisdiction is proper, we now proceed to the merits of the case.

[*1374]

B. Standards of Review

[HN2] The district court may grant a JMOL when [**15] "a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Fed. R. Civ. P. 50(a)(1). We review a district court's decision granting a motion for JMOL de novo, reapplying the JMOL standard. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 975, 34 U.S.P.Q.2D (BNA) 1321, 1326 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 38 U.S.P.Q.2D (BNA) 1461, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). On appeal, we must consider the record evidence in the light most favorable to the non-movant and draw all reasonable inferences in its favor "without disturbing the jury's credibility determinations or substituting our resolutions of conflicting evidence for those of the jury." *Id.* We will affirm the grant of JMOL if substantial evidence does not support the jury's factual findings or if those factual findings do not support the jury's legal conclusions. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986).

[HN3] Whether a new trial was properly granted is a procedural issue not unique to patent law; we therefore review the trial [**16] court's grant of a new trial under the law of the regional circuit. *Southwest Software*, 226 F.3d at 1290, 56 U.S.P.Q.2D (BNA) at 1168. In the Ninth Circuit, a grant of a new trial is reviewed for an abuse of discretion. *United States v. 4.0 Acres of Land*, 175 F.3d 1133, 1139 (9th Cir. 1999).

[HN4]

The trial court may grant a new trial, even though the verdict is supported by substantial evidence, if the verdict is contrary to the clear weight of the evidence, or is based upon evidence which is false, or to prevent, in the sound discretion of the trial court, a miscar-

riage of justice. We must uphold the district court if any of its grounds for granting a new trial are reasonable. The corollary, of course, is that a district court may not grant or deny a new trial merely because it would have arrived at a different verdict. Thus, we may find that a district court abused its discretion in ordering a new trial if the jury's verdict is not against the clear weight of the evidence.

Id. (internal quotations and citations omitted). [HN5] When the motion for a new trial is based on insufficiency of the evidence, the court should grant the motion only if the [**17] verdict is against the great weight of the evidence, or it is quite clear that the jury has reached a seriously erroneous result. *EEOC v. Pape Lift, Inc.*, 115 F.3d 676, 680 (9th Cir. 1997). n1 When granting a new trial, a trial court may weigh the evidence and credibility of the witnesses, but it may not grant a new trial "merely because it might have come to a different result from that reached by the jury." *Roy v. Volkswagen of Am., Inc.*, 896 F.2d 1174, 1176 (9th Cir. 1990).

n1 We need not consider whether there is any difference between the Ninth Circuit's use of the terms "clear weight" and "great weight" in order to decide this case.

C. Validity/Enforceability

1. Best Mode

Mentor argues that the district court erred in its grant of JMOL for defendants because Parisi, the inventor, did not consider that the circuit details constituted a "mode," let alone a best mode, for carrying out the invention. Mentor also asserts that, even if Parisi did consider the circuit [**18] details a part of the best mode, a mere technician would have been enabled to develop the circuit by the disclosure in the specification of Parisi's preferred values, viz., a 40 kHz frequency with an amplitude of 2 mil.

The defendants respond that Parisi's trial testimony, in which he stated that the circuit used to stabilize the frequency was important for the liposuction procedure to work as intended, establishes Parisi's subjective contemplation of a best mode. The defendants further assert that one of skill in the art would not have objectively understood that Parisi's best mode was in fact disclosed in the specification. Finally, [*1375] the defendants argue that this stabilization circuit is directly related to the second

step of claim 1 of "ultrasonically vibrating said probe at substantially high frequencies and low amplitudes, creating localized tissue separation and frictional heat" because the circuit is necessary to create the optimal conditions for frictional heating and melting fat.

[HN6] A patent specification must set forth the "best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112, P 1.

Determining whether a [**19] patent fails to comply with the best mode requirement and is thus invalid involves two factual inquiries. First, the fact-finder must determine whether at the time an applicant filed an application for patent, he or she had a best mode of practicing the invention, which is a subjective determination. Second, if the inventor had a best mode of practicing the invention, the fact-finder must determine whether the best mode was disclosed in sufficient detail to allow a skilled artisan to practice it without undue experimentation, which is an objective determination.

Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1064, 46 U.S.P.Q.2D (BNA) 1097, 1101 (Fed. Cir. 1998) (citations omitted).

[HN7] The defendants bear the burden of showing facts supported by clear and convincing evidence to prove the patent invalid. *Id.* Courts grant JMOL for the party bearing the burden of proof only in extreme cases, when the party bearing the burden of proof has established its case by evidence that the jury would not be at liberty to disbelieve and the only reasonable conclusion is in its favor. *Id.* at 1064, 46 U.S.P.Q.2D (BNA) at 1102.

We agree with the jury that the defendants [**20] did not meet their burden of proving a best mode violation by clear and convincing evidence such that a reasonable jury could only conclude that the patent is invalid. While Parisi's trial testimony suggests that he did not disclose all of the details of all of his prototypes during the development of his invention, including the circuitry at issue, the invention is directed to a method of using ultrasonic vibration to create heat and melt fat. It is not directed to the particular circuitry developed by a technician that was outside of the inventor's field of expertise.

[HN8] The best mode requirement does not mandate the disclosure of each detail of prototypes made prior to filing for a patent. *Wahl Instruments, Inc. v. Acvious, Inc.*, 950 F.2d 1575, 1581, 21 U.S.P.Q.2D (BNA) 1123, 1128 (Fed. Cir. 1991). The record indicates that the defen-

dants questioned Parisi about several modifications made to his prototype devices during their development and then tried to induce him to agree that at least one of these modifications was made because he considered it "best" to make it. However, the best mode inquiry is not mechanical. This testimony, although sufficient to elicit an admission [**21] that Parisi at one time considered a particular circuit to be desirable for use with his method, does not establish that Parisi considered the circuit to be a necessary part of his invention. [HN9] An applicant is only obliged to disclose unclaimed elements when they are necessary to the operation of the invention. *Applied Med. Res. Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 1377, 47 U.S.P.Q.2D (BNA) 1289, 1291 (Fed. Cir. 1998).

We also agree with Mentor that Parisi satisfied the best mode requirement by disclosing his preferred frequencies of vibration. Even if the patent did not explicitly disclose the circuit used to maintain these frequencies in one of the prototypes, the defendants did not show at trial that one of skill in the art could not have readily selected a circuit to stabilize the frequency. See *Wang Labs., Inc. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1583, 41 U.S.P.Q.2D (BNA) 1263, 1273 (Fed. Cir. 1997). The jury apparently heard and accepted Parisi's testimony that his technician in fact developed the circuit. [*1376]

Finally, the best mode issue is one of fact, decided by the jury. Substantial evidence supports the jury's verdict. The jury may [**22] reasonably have found that Parisi did not consider the circuitry details to have been a best mode of carrying out his invention. Alternatively, the jury may have reasonably concluded that the specification's disclosure of preferred frequency and amplitude values described the best mode in sufficient detail to enable a skilled artisan, with the assistance of a technician, to practice the best mode. The district court erred in overriding the jury on this fact question, especially under a "clear and convincing" standard. We therefore reverse the district court's grant of JMOL on the ground of a best mode violation.

2. New Trial

Mentor argues that the district court, in granting a new trial on anticipation, ignored the explicit limitation of claim 1 that heat is used to melt fat, and that this limitation is taught nowhere in the prior art. The defendants assert that the '363 patent teaches the creation of frictional heat caused by the vibrations of the operating tip. This heat, according to the defendants, inherently melts any fatty tissue surrounding the tip. The defendants rely solely on testimony in asserting that the '363 patent teaches the removal of animal fatty tissue from a [**23] patient. The defendants also assert that the Cavitron 510(k) applica-

tions disclose each element of the claimed invention, including the inherent characteristics of frictional heat and melting.

We conclude that the jury's verdict was not against the great weight of the evidence. Mentor correctly asserts that the '363 patent has no express disclosure concerning melting fat and in fact teaches that heat should be minimized so as to avoid damaging the surrounding tissues. '363 patent, col. 1, ll. 4-11. Similarly, the Cavitron 510(k) applications disclosed nothing about heating or melting. Despite the lack of teaching of the melting limitation, the district court concluded that "the '363 patent teaches every element claimed in the '491 patent through a step-by-step description of the device being used to remove unwanted soft tissue." Mentor II at 3. In addition, it found that "the 510(k) applications identify each element necessary for a finding of anticipation, including use of the CUSA device for [liposuction]." Id. The district court, however, did not note the failure of the references to explicitly teach melting fat or even try to identify how the references purportedly anticipated [**24] this claim limitation. Id. It did not articulate any reliance on the doctrine of inherent anticipation. Id. The trial testimony, moreover, does not cure the deficiency of these references to explicitly anticipate the '491 patent by establishing inherent anticipation.

To support their inherent anticipation argument, the defendants cite the testimony of Mentor's own expert, Dr. Langer, in which he admits that the prior art generates heat. He does not say how much heat is generated, however, and the testimony is inconclusive as to whether or not a sufficient amount of heat is generated to melt fat. Id. Dr. Langer testified that the '363 patent did not teach a melting step. Id. at 1906. Defendants' witness, Mr. Wuchinich, testified that fat exists as a liquid in vivo, obviating the melting step. Id. at 1385. The trial testimony does not meet [HN10] the threshold for showing inherent anticipation, which may not be established by "probabilities or possibilities." See *MEHL/Biophile Int'l Corp. v. Milgram*, 192 F.3d 1362, 1365, 52 U.S.P.Q.2D (BNA) 1303, 1305 (Fed. Cir. 1999) (citing *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. (BNA) 323, 326 (CCPA 1981)). [**25] "The mere fact that a certain thing may result from a given set of circumstances is not sufficient." Id. Moreover, the jury found this evidence insufficient to anticipate the claims. Although the court may itself weigh the evidence and credibility of the witnesses, *Roy*, 896 F.2d at 1176, it may not substitute its judgment for the jury's. The court, in conclusory fashion, asserted that the references anticipate the claim [*1377] limitations, an assertion unsupported by the record in light of the defendants' burden to prove facts establishing anticipation by clear and convincing evidence. See *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2D (BNA)

1051, 1053 (*Fed. Cir.* 1987). We thus reverse the district court's grant of a new trial on anticipation.

The district court also granted a new trial on obviousness. In asserting error, Mentor argues that the defendants did not show any motivation to combine references because the prior art universally teaches away from melting. Mentor also asserts that the district court committed reversible error in failing to consider Mentor's evidence of secondary considerations of nonobviousness, such as its commercial [**26] success. The defendants argue that the differences between the claimed invention and the prior art references are slight, and that one of ordinary skill in the art would have understood that frictional heat is an inherent by-product of the prior art devices and that it would melt fat.

For the same reasons as discussed with respect to the anticipation issue, we conclude that the district court abused its discretion in granting a new trial for obviousness. In support of its grant of a new trial, the court asserted that the '363 patent and two other patents (U.S. Patents 4,223,676 and 4,425,115) disclose the teachings of the '491 patent, without identifying how those references disclose the claim limitation of melting fat. The court also failed to articulate any motivation to combine the references. The record evidence does not clearly support the court's assertion that the cited references render the claimed invention obvious. Rather, the '363 patent can also be said to teach away from the beneficial use of heat. '363 patent, col. 1, ll. 4-11. Each of the patents teaches that a cooling fluid should be used to cool the site of tissue removal. '363 patent, col. 3, ll. 67-70; col. 8, ll. [**27] 27-29; '676 patent, col. 7, ll. 55-58; '115 patent, col. 7, ll. 38-42. One of ordinary skill in the art cannot clearly be said to have been motivated by these references to arrive at the claimed invention of melting fat. The defendants thus did not meet their burden to show obviousness by facts supported by clear and convincing evidence. Accordingly, because the jury's verdict was not against the great weight of the evidence, we reverse the grant of a new trial on obviousness.

The district court also granted a new trial on the issue of inequitable conduct. In asserting error, Mentor argues that the '363 patent is merely cumulative of other prior art describing devices that fragment tissue, but do not melt it. Mentor also asserts that the '363 patent was discussed extensively in U.S. Patent 4,136,700, which was before the examiner. Mentor further argues that the defendants did not show that Parisi intended to withhold the reference, and that the district court erred by not considering the intent prong in its inequitable conduct analysis. The defendants respond that deceptive intent may be inferred from Parisi's conduct, viz., copying the '363 abstract into

his invention disclosure, [**28] but not disclosing the '363 patent to the PTO.

[HN11] A defendant asserting an inequitable conduct defense must demonstrate by clear and convincing evidence that the applicant or his attorney failed to disclose material information to the PTO, and that the applicant or his attorney did so with intent to deceive the PTO. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178, 33 U.S.P.Q.2D (BNA) 1823, 1826 (*Fed. Cir.* 1995). Inequitable conduct is an equitable issue committed to the discretion of the district court. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1570, 43 U.S.P.Q.2D (BNA) 1398, 1407 (*Fed. Cir.* 1997).

The allegedly material information not disclosed to the PTO in this case consists of the '363 patent and Parisi's opinions regarding the Cavitron devices. We have already determined that the district court abused its discretion by granting a new trial on anticipation by these references. We must now address [**1378] whether these references, although not clearly anticipatory, are nevertheless material to patentability. These disclosures are not material if they are merely cumulative of references that were already before the examiner. *Regents*, 119 F.3d at 1574-75, 43 U.S.P.Q.2D (BNA) at 1411. [**29] We agree with Mentor that the record indicates that the references were merely cumulative of the prior art on ultrasonic devices that fragment tissue.

The '363 patent was discussed extensively in the '700 patent that was before the examiner. The '700 patent states that the claimed apparatus does not generate sufficient heat to damage any adjacent tissue, which the examiner noted in the Statement of Reasons for Allowance. '700 patent, col. 3, ll. 19-21; Paper No. 6, May 19, 1989. Similarly, the '363 patent provides a sheath to avoid the possibility of heat damaging surrounding tissue. '363 patent, col. 7, ll. 60-65. Although these disclosures suggest that devices covered by the '363 patent may generate more heat than those covered by the '700 patent, we discern no significant difference in materiality between these disclosures. The '700 patent is more material in at least one respect because it is directed to ultrasonic vibration on soft tissue. '700 patent, col. 1, l. 41 - col. 2, l. 2. We therefore conclude that the '363 patent is merely cumulative of art already considered by the examiner.

The defendants have also failed to show by clear and convincing evidence that the applicants [**30] intended to deceive the PTO. They assert that Parisi's intent may be inferred because he copied the abstract of the '363 patent into his invention disclosure statement. This invention disclosure statement, however, was not part of the '491 patent. Rather, it was only an internal document. Parisi appears to have drawn from the language of the

known prior art '363 patent to describe his invention for his own non-public purposes. Parisi's invention disclosure statement even expands upon the '363 abstract just as his invention does. He discusses the breaking up of "fat tissue," which is notably absent from the '363 abstract's discussion of breaking up unwanted tissue, such as cataracts. Moreover, Parisi did not present his invention disclosure statement to the PTO as a description of his invention in support of its patentability. The defendants established only that Parisi probably knew of the cumulative '363 reference. Mere knowledge of that reference, which we have held to be merely cumulative of other prior art, is not an indication of an intent to deceive. The district court abused its discretion by inferring intent to deceive the PTO from this fact of knowledge.

Similarly, the district court abused its discretion by imposing the requirement that the applicants provide the PTO with Parisi's opinions regarding the Cavitron device. An inventor's opinions regarding a prior art device known to the examiner are not within the domain of material that must be submitted to the PTO. An article describing the device was before the examiner and the record does not demonstrate that Parisi misrepresented the device. The court erred by inferring an intent to deceive the PTO on these facts. Because the jury's verdict was not against the great weight of the evidence, we reverse the court's grant of a new trial on inequitable conduct.

D. Infringement

1. Misonix

Mentor argues that substantial evidence supports the jury's verdict that the defendants infringed both contributory and by inducement and that the district court therefore erred in granting a JMOL of non-infringement by Misonix. The defendants do not specifically defend the court's JMOL. Rather, on cross-appeal, the defendants argue that they are entitled to a judgment of non-infringement under their proposed claim construction, or, alternatively, under a correct application of the court's claim construction. The defendants also request a new trial on claim construction if we deny their cross-appeal for a judgment of non-infringement.

We agree with Mentor that the district court erred by granting Misonix JMOL of non-infringement for contributory and inducement of infringement. With respect to contributory infringement, Mentor offered substantial evidence at trial that Lysonix 2000 was not a staple item suitable for substantial noninfringing use under 35 U.S.C. § 271(c) (Supp. IV 1998). See *C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc.*, 911 F.2d 670, 674, 15 U.S.P.Q.2D (BNA) 1540, 1543 (Fed. Cir. 1990). The defendants' manual states that Lysonix 2000 was "specif-

ically manufactured for plastic and cosmetic surgeons interested in removing the soft tissue layer that resides between the skin . . . and the deep fascia." This procedure is an ultrasonic liposuction method. The jury was entitled to reject Misonix's assertions that Lysonix 2000 had other potential uses because the record does not indicate any actual uses of the device other than ultrasonic liposuction.

With respect to inducing infringement under 35 U.S.C. § 271(b) (1994), [**33] Mentor met its burden to show that Misonix's actions induced infringing acts and that Misonix knew or should have known that its actions would induce actual infringement. See *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553, 16 U.S.P.Q.2D (BNA) 1587, 1594 (Fed. Cir. 1990). Mentor established at trial that Misonix knew of the existence of the patent because it was denied a license and received a cease-and-desist letter concerning it. Yet Misonix chose to continue selling the Lysonix 2000 devices to MDA/Lysonix pursuant to an agreement covering ultrasonic machines designed specifically for use in performing ultrasonic liposuction. Although Misonix presented a non-infringement opinion letter, the jury nonetheless found willful infringement, apparently discrediting Misonix's assertion that it relied in good faith on an opinion of counsel. Substantial evidence thus supports the jury's verdict that Misonix induced infringement because it sold the device with the intention that doctors would use it to perform the patented method. Accordingly, we reverse the court's JMOL of non-infringement with respect to Misonix.

The district court denied the defendants' motion for [**34] a new trial on inducement of infringement with respect to Lysonix and MDA, but indicated that it would grant a new trial to Misonix in light of its previous grant of Misonix's motion for JMOL of no inducement of infringement. We must therefore decide if the district court abused its discretion in granting a new trial to Misonix for inducement of infringement. Because Mentor presented evidence that Misonix knew or should have known that its products would be used in the patented method, we conclude that the district court abused its discretion in granting a new trial to Misonix on this issue. Thus, we reverse the district court's grant of a new trial to Misonix on inducement of infringement.

2. All Defendants

The district court granted the defendants' motion for a new trial on contributory infringement. Mentor argues that the evidence does not support the court's conclusion that Lysonix 2000 is a staple article under 35 U.S.C. § 271(c) because the record does not demonstrate that Lysonix 2000 has ever been used for anything other than the patented procedure. The defendants assert that Mentor

has not appealed the court's conclusion that MDA and Lysonix are entitled [**35] to a new trial on contributory infringement. We disagree. Although Mentor's arguments are primarily directed to whether Misonix had infringed, Mentor stated in a heading in its brief that the court abused its discretion in granting a new trial on contributory infringement. Because the district court granted a new trial on contributory infringement with respect to all of the defendants, we conclude that Mentor did effectively appeal the district court's new trial holding with respect to Lysonix and MDA. [*1380]

The defendants do not address Mentor's arguments that Lysonix 2000 is not a staple article of commerce. Rather, they seek a judgment of non-infringement based on a different claim construction or, alternatively, a new trial on claim construction. We have already held that substantial evidence supports the jury's verdict that Lysonix 2000 was especially adapted for use in the claimed method. For the same reasons, which are unrebutted by the defendants on appeal, we also hold that the district court abused its discretion in determining that the jury's verdict was against the great weight of the evidence. We therefore reverse the district court's grant of a new trial on contributory infringement [**36] with respect to all of the defendants.

E. Enhanced Damages and Attorney Fees

Mentor argues that the district court erred in not considering all the relevant circumstances in its denial of Mentor's motion to increase damages and award attorney fees, and that we should vacate this ruling if we reverse on the best mode violation. The defendants respond that a finding of willful infringement is not dispositive of an award of enhanced damages and attorney fees, and that we should not overturn this discretionary determination of the trial judge.

[HN12] Assessing increased damages is a two-step process. *Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1570, 38 U.S.P.Q.2D (BNA) 1397, 1399 (Fed. Cir. 1996). First, the fact-finder must determine if an accused infringer is guilty of conduct, such as willfulness, upon which increased damages may be based. *Id.* If so, the court then exercises its discretion to determine if the damages should be increased given the totality of the circumstances. *Id.* We agree with the defendants that the district court did not abuse its discretion in denying enhanced damages and at-

torney fees. The court found that "enhanced damages are inappropriate because [**37] the question of willfulness was 'sufficiently close on the evidence.'" Mentor I at 7. The court considered evidence of willfulness but found that it was "not as strong as it could have been and [was] not of the weight and strength that would support the imposition of enhanced damages." *Id.* Similarly, the court denied Mentor's motion for attorney fees because "the case was very close and . . . exceptional circumstances do not exist." Given the closeness of the case and the discretionary nature of its decision, we affirm the district court's denial of Mentor's motion for enhanced damages and attorney fees.

F. Cross-Appeal on New Claim Construction

The defendants argue that the court committed reversible error by refusing to construe the claim terms "irrigating" and "frictional heat." Mentor argues that the court properly instructed the jury that these terms should receive their ordinary meanings. We agree with Mentor that the district court did not err in relying on the ordinary meanings of these terms. See *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 989, 50 U.S.P.Q.2D (BNA) 1607, 1610 (Fed. Cir. 1999) (setting forth a heavy presumption in favor [**38] of the ordinary meaning of claim language). We thus conclude that the district court did not abuse its discretion in denying the defendants a new trial on claim construction.

CONCLUSION

Because the jury's verdict was supported by substantial evidence, we reverse the district court's grant of JMOL on the ground of a best mode violation. As the jury's verdicts on anticipation, obviousness, and inequitable conduct were not against the great weight of the evidence, we similarly reverse the court's grant of a new trial on those issues. We also reverse the court's grant of a JMOL of non-infringement by Misonix, and its grant of a new trial on contributory infringement. However, we affirm the court's denial of enhanced damages and attorney fees. We [*1381] have considered and rejected the defendants' cross-appeal and remaining arguments. Accordingly, we

AFFIRM-IN-PART and REVERSE-IN-PART.

COSTS

Each party shall bear its own costs.